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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,821	12/15/2005	Tsunenori Arai	011350-367	9015

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EXAMINER	
SHAY, DAVID M	

ART UNIT	PAPER NUMBER
3769	

NOTIFICATION DATE	DELIVERY MODE
12/18/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/560,821	ARAI ET AL.	
	Examiner	Art Unit	
	david shay	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *October 19, 2009*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-15,17,18 and 22-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-15,17,18 and 22-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *October 19, 2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

As an initial matter, it is noted that applicant has removed from the claims all recitations of the form "means for [function]" as such, these terms, even though still incorporating the term "means" no longer satisfy the three pronged test for means plus function language, and are considered to be outside of recitations controlled by 35 U.S.C. 112, sixth paragraph.

With respect top the drawings, applicant argues that the drawings are discussed at pages 21-23 of the originally filed disclosure. While the examiner appreciates this, it does not bring the drawings into conformance. It is further noted that 37 C.F.R. 1.83(a) specifically states that "The drawing in a non-provisional application must show every feature of the claimed invention specified in the claims. However, conventional features disclosed in the description and claims, where their detailed illustration is not essential for a proper understanding of the invention, should be illustrated in the drawing in the form of a graphical drawing symbol or a labeled representation (*e.g.*, a labeled rectangular box)…". Clearly the requirement for a symbol or labeled graphical representation is a requirement for an illustration which is readily comprehensible to an observer as to what it represents. This is reiterated and clarified in 37 C.F.R. 1.84(n), which is reproduced below for applicant's convenience:

(n) *Symbols* . Graphical drawing symbols may be used for conventional elements when appropriate. The elements for which such symbols and labeled representations are used must be adequately identified in the specification. Known devices should be illustrated by symbols which have a universally recognized conventional meaning and are generally accepted in the art. Other symbols which are not universally recognized may be used, subject to approval by the Office, if they are not likely to be confused with existing conventional symbols, and if they are readily identifiable.

Kindly note that symbols and labeled representations are set forth as alternatives in 37 C.F.R. 1.83(a) and therefore are equivalent. Further, kindly note that the requirement for the use of symbols and labeled representations is set out separate and apart from the requirement for

reference numerals. Also kindly note that known devices "should be illustrated by symbols which have a universally recognized conventional meaning…". Since applicant has chosen to employ unlabeled representations, rather than the labeled representations clearly called for in 37 C.F.R. 183(a) and 1.84(n), the drawing objections have been maintained and applicant's arguments are not convincing.

With regard to the specification, applicant traverses the examiners objection thereto and requests withdrawal of the objection. The examiner has reconsidered the objection to the specification, but cannot withdraw the objection. The continued use of terms such as cell death rater and cell fatality rate as though they have distinct different meanings, for example, does not warrant the withdrawal of the objection.

The rejection under 35 U.S.C. 101 has been remedied by applicant's amendments.

While applicant's comments regarding optical power are noted, it is also noted that the originally filed disclosure is completely devoid of any discussion whatsoever of optical power. Concerning the rate of cell death and cell fatality rate, while the examiner understands that applicant is his own lexicographer, and while defining the rate of cell death, not as the rate at which cells die, but the rate at which they are injured is within applicant's right, defining the cell fatality rate as "meets a criterion for the rate of cell death, in which function of the organ becomes unrecoverable by an action of the photosensitive substance" is too vague to place within the grasp o one of ordinary skill in the art what applicant is referring to. A rate is universally recognized as how much something occurs compared to the change of another variable, usually time. However, the definition on page 19 of the originally filed disclosure appea4rs to describe some sort of threshold, rather than a rate.

It is further noted that while applicant discusses various peak intensities in the originally filed disclosure, there are not values given, nor any metric for determining the peak intensities which are appropriate for treatment versus those which will not activate the photosensitizer in the intervening healthy tissue. Thus, as these peak intensities are not disclosed, they are assumed to be within the knowledge of one of ordinary skill in the art.

The drawings are objected to because elements 11, 12, 13, 14, and 20-24 in Figure 4 are not labeled with indicia indicative of their function. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "input means for being input a preserved distance" and the "controlling not to activate the photosensitive substance in the

superficial part of the body located close to the light irradiation means then the lesioned part" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The amendment filed September 22, 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "controlling the intensity of light with or without changing an optical power".

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 5-15, 17, 18, and 22-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. "controlling the intensity of light with or without changing an optical power".

Claims 1-3, 5-15, 17, 18, and 22-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 13, and 17 recite the limitation "controlling the intensity of light with or without changing an optical power". The terms are not clearly defined in that lacks positive antecedent basis in the originally filed disclosure. Claim 29 recites the limitation "controlling the intensity of light with or without changing a light quantity". The terms are not clearly defined in that lacks positive antecedent basis in the originally filed disclosure. Further, claims 1, 13, 17 and 29 are incomplete, as they provide no means or steps by which the intensity of the light at certain depths for any general tissue is sensed or determined. Still further, in claim 1 the term

“the lesioned partcontrols” lacks positive antecedent basis. Claim 10 is unclear as the term "not changing the total number of pulse of the light irradiated from the irradiation means, but by controlling the peak intensity of the light" is not clear as it lacks positive antecedent basis in the originally filed disclosure and “the peak intensity lacks positive antecedent basis. Claim 11 is indefinite as directed to intended use. The total energy is related to intensity over time and therefore is dependent on the time of treatment. Claim 12 is unclear as a peak intensity has, by definition, a single value, yet the peak intensity is cited as changing, further “the peak” lacks positive antecedent basis. Claim 13 recites the limitation "the photodynamic therapy" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 13 recites the limitation "the wavelength" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. Claims 13 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: determination of tissue type or attenuation properties of the tissue and a determination of the boundaries of the target and non-target areas. The depth limits of the superficial part would be required inputs for an intensity calculation. In claim 14, “the repetition frequency” lacks positive antecedent basis. Claim 17 is indefinite due to the term "and controls a rate of cell death damaged by an action of the photosensitive substance”, which appears to require controlling the rate of cell death, which is defined as the rate of cells damaged by the action of activation of the photosensitive substance, damaged by an action of the photosensitive substance; in other words, it appears that the rate of cell death is damaged by the photosensitive substance, which appears to imply that the cells are not damaged. Claim 18 is indefinite as the term "total number of a irradiation pulse" is not clear and “the peak intensity”

lacks positive antecedent basis. In claims 22-25 the limitations "the cell fatality rate" and "the peak intensity" lack positive antecedent basis, further the claim is indefinite because it is unclear what, if any further limitation is recited by controlling "the range of the cell fatality rate", since, as set forth above, according to the specification the "cell fatality rate" appears to be a threshold above which the organ cannot survive the treatment, rather than the rate at which some event occurs. it is unclear what the difference between "the rate of cell death" and "the cell fatality rate" as these appear to be the same thing, and thus how one is controlled to be above the other is unclear, the disclosure at paragraph [0079] of the PGPub, also the last full paragraph on page 19 of the originally filed disclosure, which appears to assert a difference therebetween but does not articulate such difference in a manner understandable to the examiner, notwithstanding. Claim 23 is indefinite as the term "total number of the irradiation pulse" is not clear. Claim 23 recites the limitation "the cell fatality rate" in line 4. There is insufficient antecedent basis for this limitation in the claim. Claim 24 is unclear as a peak intensity has, by definition, a single value, yet the peak intensity is cited as controlled or changing. Claim 24 recites the limitation "the cell fatality rate" in line 4. There is insufficient antecedent basis for this limitation in the claim. Claim 25 recites the limitation "the cell fatality rate" in line 4. There is insufficient antecedent basis for this limitation in the claim. Claim 29 recites the limitation "the high peak intensity" in line 13. There is insufficient antecedent basis for this limitation in the claim.

Claim 1, 2, 5, 6, 10-12, 17 and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bower et al (WO '842). Bower et al (WO '842) teaches providing light at a desired intensity level to a target tissue, wherein the endoscope is regarded as a catheter. It would have been obvious to one skilled in the art to configure the intensity of the light such that

it was too high to activate the photosensitizer in the intervening healthy tissue, since it is well known in the art that it is undesirable to kill healthy tissue, thus producing a device and method such as claimed.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Bower et al (WO '842). as applied to claim 1 above and further in view of U.S. Patent Application Publication US 2003/0022105 to Prasad et al. Bower et al (WO '842) is discussed above, but do not teach intensities or pulse rates. Prasad et al. discloses intensities for photodynamic therapy of from 0 to 200 MW/cm2 (paragraph 0321) and pulse rates of from 0.1 Hz to 1 kHz (paragraph 0334). Control of light parameters in photodynamic therapy is pervasive in the art and, therefore, it would have been obvious to one skilled in the art to use the intensities and pulse rates as taught by Prasad et al. in the device of Bower et al (WO '842) to obtain the light parameters required for a specific photosensitizer.

Claims 7-9 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bower et al (WO '842). as applied to claims 1 and 17 above and further in view of U.S. Patent 5,514,669 to Selman. Bower et al (WO '842) is discussed above, but do not teach the use of a balloon catheter for delivery of light for photodynamic treatment. Selman teaches photodynamic therapy wherein the light energy is delivered to a patient's prostate by placing the light delivery means in a urethral catheter. The light delivery means is properly located within the urethra and positioned adjacent to the target prostate tissue. A balloon may be affixed to the distal end of the catheter (Col. 5, lines 15-25). It would have been obvious to one skilled in the art to use the catheter as taught by Selman in the device of Bower et al (WO '842) as the use of such catheters is pervasive in the arts.

Claims 13-16 and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bower et al (WO '842) in view of U.S. Patent 6,413,267 to Dumoulin-White et al. and U.S. Patent 5,145,863 to Dougherty. Bower et al (WO '842) is discussed above, but do not teach methodology for achieving an intensity at a specific depth in tissue. Dougherty teaches a method for destroying cells using photoradiation of target tissue with a photosensitizer, wherein a specific depth is known and the intensity determined for specific depths, which are considered to be a "preserved distance". With the attenuation constant known, the depth of penetration of a minimum irradiance or conversely the required irradiance for a minimum intensity at a given distance may be calculated. (Col. 18, lines 49-54). Dumoulin-White et al. disclose a method to estimate the depth dependence of intensity (i.e., the attenuation of intensity as a function of depth) in tissue being treated. For example, the radial dependence can be used to generate a curve or formula for a curve, which can in turn be used to select a depth dependence curve or formula from a look-up table. In any event, the intensity (or irradiance) of radiation at target depth is determined from the depth dependence curve or formula, and the radiant exposure at target depth is determined by, e.g., integration (Col. 5, lines 40-49). An inherent feature of all photosensitizers is a range of activation. It would have been obvious to one skilled in the art to use the techniques for determining an intensity at specific depths in tissue as taught by Dougherty and Dumoulin-White et al. to control the radiation of Bower et al (WO '842) to control a photodynamic process. A skilled artisan would know the activation characteristics of the photosensitizer used and the depths to be treated and would be motivated to insure the proper intensity required was delivery at the proper location or locations. Regarding claim 30, the

various methods for delivery of a photosensitizer and well known in the art (see Selman cited above).

Applicant's arguments with respect to claims 1-3, 5-15, 17, 18, and 22-30 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Monday through Thursday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson, can be reached on Monday through Friday from 7:00 a.m. to 3:30 p.m. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/

Primary Examiner, Art Unit 3769